

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/523,243	§	Confirmation No.:	6495
Applicant:	Michael Brock et al.	§		
Filed:	10/12/2005	§		
TC/A.U.:	1617	§		
Examiner:	Soroush, Layla	§		
Title:	Microemulsion Containing UV Filters and/or Anti-Dandruff Agents	§		
Docket No.:	Muller-47	§		

**DECLARATION OF Michael Brock
PURSUANT TO 37 CFR §1.132**

I, Michael Brock, declare as follows:

I am currently a R&D-Manager with Sasol Germany GmbH as set forth in my Curriculum Vitae, attached hereto as Exhibit 1.

As can be seen from Exhibit 1, I have had extensive experience in microemulsions for cosmetic applications.

I am a Inventor on the captioned application and have reviewed the outstanding Office Action and the references cited by the Examiner, i.e., Brock et al. (WO 00/47166), Hasegawa (JP 06234628A), Domsch et al. (DE 10058328A1) and Ansmann et al. (US 6,365,168 B1).

It is my opinion that the combination of Brock et al. (WO 00/47166), Hasegawa (JP 06234628A), Domsch et al. (DE 10058328A1) and Ansmann et al. (US 6,365,168 B1) does not render the claimed invention of the captioned application obvious as I understand that concept.

I note in the Office Action that the Examiner recognizes that the Brock et al. reference does not teach the use of UV filters or antidandruff agents with the composition of Brock et al.

I further note that the Examiner has cited the references to Hasegawa, Domsch et al. and Ansmann et al. simply to show antidandruff agents (Hasegawa and Domsch et al.) and UV filters (Ansmann et al.).

I further note that the rejection is that it would be obvious to incorporate UV filters and antidandruff agents into the composition of Brock et al. because a skilled artisan would have reasonable expectation of successfully producing a stable, medicinal-dermatologic-microemulsion by incorporating the UV filters and antidandruff agents.

Attached to this Declaration are Exhibits A-G which in my opinion demonstrate that the claimed invention is patentable over the prior art references cited by the Examiner.

Exhibits A-F document experimental work done by an independent company in a double-blind trial fashion sponsored via IFAC GmbH & Co., KG by the Assignee of the present application. Exhibit G is a copy of a publication, Sunscreen Formulation and Testing, Michael Caswell, PhD, dated September 2001, to be discussed later.

With respect first to Exhibit A, the efficacy of six antidandruff shampoos was investigated, Exhibit A setting forth the details of the actual study. Exhibit B, detailing the compositions of Products 1-6. Products 1 and 2 are comparative, prior art antidandruff shampoos preparation, while Products 3-6 are antidandruff shampoos made in accordance with the present invention, i.e., using the microemulsion composition set forth in (A)-(D) of Claim 1 (Claimed Microemulsion). As can be seen from Exhibit A, antidandruff shampoos produced using the Claimed Microemulsion according to the present invention (Products 3-6) exhibit antidandruff efficacy about the same as that achieved with conventional shampoo preparations (Products 1 and 2) even though the antidandruff agent in Products 3-6 is present in amounts of 2/3 and even 1/3 of those used in the conventional shampoo preparations, Products 1 and 2. In

this regard, the Examiner's attention is respectfully directed to a comparison of Product 1 a conventional shampoo preparation containing 0.75 wt.% of Climbazole with Products 5 and 6 containing 0.25 wt.% and 0.5 wt.% Climbazole, respectively. Similar results are obtained when the antidandruff agent is Niacinamide wherein Product 2, the conventional shampoo preparation contains 0.75 wt.% Niacinamide while Products 3 and 4 using the Claimed Microemulsion according to the present invention contain 0.25 wt.% and 0.5 wt.% measurements, respectively.

The data in Exhibits A and B demonstrate that by incorporating common antidandruff agents, e.g., Climbazole and Niacinamide, in the Claimed Microemulsion, unexpected results are achieved. In this regard, the skilled artisan would not expect that by using the Claimed Microemulsion, one would achieve substantially the same antidandruff efficacy as conventional antidandruff shampoos when the amount of the antidandruff agent was reduced so dramatically.

Exhibits C and D are similar to Exhibits A and B in that the efficacy of three antidandruff shampoos was tested, the test procedure being set forth in Exhibit C, the compositions of the three compositions being set forth in Exhibit D. As can be seen from Exhibit C, one achieves essentially the same antidandruff efficacy in the products employing the Claimed Microemulsion, e.g., Products B and C of the present invention, with markedly reduced amounts of the active antidandruff agent, Octopirox, as compared with a conventional antidandruff shampoo also containing Octopirox (Product A). Again, as in the case of Exhibits A and B, the results set forth in Exhibits C and D are unexpected.

With respect to the unexpected nature of the results seen in Exhibits A-D, the expected results would have been that to achieve the same antidandruff efficacy as demonstrated by the conventional shampoo preparations, the same amount of active antidandruff agent would be

necessary when used with the Claimed Microemulsion. As demonstrated by Exhibits A-D, that is not true.

With respect to Exhibits E and F, Exhibit E sets out a comparative test between two shower gels identified as Duschgel 1 and Duschgel 2, both Duschgel 1 and Duschgel 2 being microemulsions, Duschgel 2 containing a commonly used sunscreen agent, Parsol MCX. The compositions of Duschgel 1 and Duschgel are set out in Exhibit E.

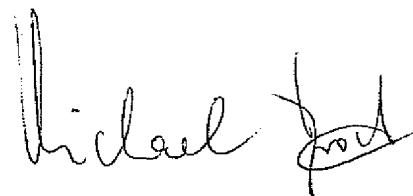
As can be seen from the data in the table on page 3 of Exhibit F, Duschgel 2, using the Claimed Microemulsion and the sunscreen agent, Parsol MCX, exhibits UV filtering capacity twice as high as the straight microemulsion without any sunscreen additive. This is a surprising result since shower gels are intended to be rinsed off and accordingly their residence time on the skin is relatively short. However, as shown by the results of Exhibits E and F, if one employs the Claimed Microemulsion as the carrier for the sunscreen agent, even after rinsing, significant residual protection against UV radiation remains on the skin. The skilled artisan would have no reason to believe that by incorporating a sunscreen agent into the Claimed Microemulsion of the present invention, such lasting UV protection would be obtained.

With respect to Exhibit G, it can be seen that a composition with an SPF of 2 absorbs 50% of UV radiation while a composition with an SPF of 3 to 4 absorbs 72% of the UV radiation. Thus, markedly increased protection against UV radiation is achieved when a UV filter is included in the Claimed Microemulsion of the present invention. Once again, this is unexpected, since as noted, shower gels are always rinsed off after use and their application time to the body is relatively short.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these

statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 2008-09-12

A handwritten signature in black ink, appearing to read "Michael J. Ford". The signature is written in a cursive style with a large initial "M" and a stylized "J" and "F".